Assembly Bill No. 1215

Passed the Assembly May 6, 2013

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Chief Clerk of the Assembly

Passed the Senate August 15, 2013

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Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2013, at _____ o'clock ___M.

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Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 1204 and 1209 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1215, Hagman. Clinical laboratories.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law prohibits the performance of a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) unless the test or examination is performed under the overall operation and administration of a laboratory director. Existing law defines "laboratory director," for purposes of a clinical laboratory test or examination classified as waived, as an individual who, among others, is a duly licensed naturopathic doctor. Existing law defines "laboratory scientist" and authorizes a person licensed as a clinical laboratory scientist and qualified under CLIA to perform the duties and responsibilities of a technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in certain specialties.

This bill would expand the definition of "laboratory director" for purposes of a clinical laboratory test or examination classified as waived to include a duly licensed clinical laboratory scientist and a duly licensed limited clinical laboratory scientist. The bill would authorize a person licensed as a clinical laboratory scientist and qualified under CLIA to additionally perform the duties and responsibilities of a waived laboratory director, as specified under CLIA.

The people of the State of California do enact as follows:

SECTION 1. Section 1204 of the Business and Professions Code is amended to read:

1204. As used in this chapter, "clinical laboratory scientist" means any person, other than a licensed clinical laboratory

bioanalyst or trainee, who is licensed under Sections 1261 and 1262 to engage in clinical laboratory practice under the overall operation and administration of a laboratory director, unless serving as a director of a waived laboratory as provided in Section 1209. A person licensed as a clinical laboratory scientist and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a waived laboratory director, as specified under CLIA, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, or other specialty or subspecialty specified by regulation adopted by the department. A person licensed as a "clinical laboratory scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

SEC. 2. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) As used in this chapter, "laboratory director" means any person who is a duly licensed physician and surgeon, or, only for purposes of a clinical laboratory test or examination classified as waived, is a duly licensed clinical laboratory scientist, a duly licensed limited clinical laboratory scientist, a duly licensed naturopathic doctor, or a duly licensed optometrist serving as the director of a laboratory which only performs clinical laboratory tests authorized in paragraph (10) of subdivision (e) of Section 3041 that are classified as waived, or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory. The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(b) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including

administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.

(c) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(d) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the

type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(e) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(f) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(g) Subdivision (f) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

(h) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

Approved _____, 2013

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Governor